FYI

NATIONAL FOREIGN INTELLIGENCE BOARD

Memorandum for Holders-2
NFIB-27.7/4

1 November 1977

MEMORANDUM FOR NATIONAL FOREIGN INTELLIGENCE BOARD

FROM : Walter Elder
Executive Secretary

SUBJECT : Guidelines for Human Subject Research within the Intelligence Community

REFERENCE: Memorandum for Holders-1 of NFIB-27.7/4 dated 17 May 1977

1. The enclosed memorandum from the Chairman, Human Resources Committee and its attachments on the subject are forwarded for your consideration.

NFIB ACTION REQUESTED

2. You are requested to forward your comments on the revised draft of the proposed directive (Tab A) as well as the issues discussed in paragrpahs 4 and 5 of Ambassador Little's memorandum to the Executive Secretary by close of business, 14 November.

[redacted]
Walter Elder

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Attachment:
As Stated

(EXECUTIVE REGISTRY FILE C-1,12.1)

COPY 1 of 30

Attachment to
Memorandum for Holders-2 of
NFIB-27.7/4

1 November 1977

MEMORANDUM FOR: Executive Secretary, NFIB

FROM: Ambassador Edward S. Little
Chief, Human Resources Division

SUBJECT: Guidelines for Human Subject Research
Within the Intelligence Community

1. This memorandum addresses several associated actions involving the protection of human subjects in research conducted within the Intelligence Community.

2. As you recall, the Board addressed an earlier version of a proposed DCID 1/12, and member agencies provided written comments. At the same time copies of the proposed guidelines were made available to the Department of Health, Education and Welfare and the National Commission for the Protection of Human Subjects in Biomedical and Behavioral Research. The CIA recommended a number of important changes. The effect of these changes together with the interest in the subject expressed recently by the Senate Select Committee during its review of Community testing involving human subjects suggest that the NFIB should review these matters.

3. This version of the proposed DCID (Tab A), which incorporates many of the changes proposed by DHEW, the National Commission, and CIA, has also been modified to be in consonance with the draft Executive Order on U.S. Intelligence Activities.

4. There are two important questions that are not specifically addressed in the proposed DCID. It would be useful for the DCI to have the benefit of NFIB Principals' comments on the substance of these issues as well as on their inclusion in the proposed DCID when he considers the total package. These questions are:

a. What, if any, additional review mechanism beyond those in the DHEW guidelines is required as regards classified research on human subjects? The National Commission favors a second review of classified research protocols by the National Commission, or alternatively by the Senate Select Committee. Under the current CIA guidelines, DHEW reviews and certifies all assurances of compliance with DHEW directives whether classified or not. The review of an

assurance is not the same as the review of a research protocol. This difference may require explanation to NFIB members by someone technically competent in this area.

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5. Senator Inouye has asked for the views of NFIB on the suggestions contained in the letter from the National Commission (Tab B). Most of Dr. Ryan's concerns are dealt with in the revised guidelines. The principal exception is the issue referred to in paragraph 4a above. Whatever comments we receive from the Board on that subject, we will use to reply to Senator Inouye.

Edward S. Little

Attachments:
A. Proposed DCID 1/12
B. Letter to NFIB from Chairman, National Commission

(13 October 1977)

TAB

Approved For Release 2004/02/19 : CIA-RDP80M00165A000500260001-1

6 October 1977

DIRECTOR OF CENTRAL INTELLIGENCE DIRECTIVE NO. 1/12

GUIDELINES FOR HUMAN SUBJECT RESEARCH
WITHIN THE INTELLIGENCE COMMUNITY

(Effective)

Pursuant to Section 102 of the National Security Act of 1947, Executive Order _____, and National Security Council Intelligence Directives, guidelines are hereby provided for the protection of human subjects in research undertaken or sponsored by the Intelligence Community.

1. Purpose

The purpose of this directive is to provide guidance to the Intelligence Community in the implementation of Executive Order _____, as it pertains to restrictions on experimentation on human subjects. All research related to intelligence missions and functions conducted, contracted for, or sponsored by any element of the Community that makes use of human subjects will be in accordance with:

a. ethical concerns for the preservation of human life, rights, and dignity,

b. all applicable statutes, Executive Branch directives, and agency or department regulations, and

c. procedures established to protect intelligence sources, methods, or data in research.

2. Applicability

a. The procedures and guidelines described or referred to herein apply to all research involving human subjects, classified or unclassified, related to national foreign intelligence production and collection and other activities in support thereof, conducted, contracted for, or sponsored in any way by Intelligence Community agencies.

b. Data collected in the normal course, or as by-products of approved administrative or operational actions, are not subject to

the guidance provided in this directive. Such data may be used in formal research projects if the confidentiality and rights of human subjects are safeguarded by procedures established by the Institutional Review Board of the Intelligence Community department or agency proposing to conduct research utilizing the data.

3. General

a. Executive Order _____, Section 4, paragraph c, Restrictions on Experimentation states: "Foreign intelligence organizations shall not sponsor, contract for, or conduct research on human subjects except in accordance with the guidelines issued by the Department of Health, Education and Welfare (DHEW). Documentation of informed consent shall be in accordance with the procedures described in the guidelines of the Department of Health, Education and Welfare."

b. DHEW guidelines are provided in the Code of Federal Regulations, Title 45, Public Welfare, Part 46, Protection of Human Subjects (45 CFR 46) and are revised periodically. These regulations represent the minimum acceptable standards for the protection of human subjects in research. The DHEW guidelines incorporate appropriate recommendations of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.

4. Responsibilities

Heads of departments, agencies, or bureaus are individually responsible for implementation of the provisions of Section 4, paragraph c of the Executive Order. It is recommended that agencies publish their own regulations for this purpose.

5. Additional Guidance

a. Institutions with which Intelligence Community organizations sponsor, contract for, or conduct research on human subjects must:

(1) assume responsibility for: (i) compliance with 45 CFR 46, all applicable statutes, and Executive Branch Directives and agency or department regulations supplied by the sponsoring department or agency; and (ii) providing adequate protection for the rights and welfare of human subjects at risk.

(2) have an approved assurance from the Department of Health, Education, and Welfare (Office for Protection from Research Risks) appropriate for the proposed research activity.

(3) provide adequate documentation of review and approval of the proposed research activity by an Institutional Review Board.

(4) maintain records of research on human subjects, particularly when risk of harm is involved and such harm may not become known until after the research has been completed. These records will enable subjects to be contacted for follow-up examination and facilitate proper review of research-related injuries.

b. Intelligence Community organizations shall monitor and inspect activities of those institutions with which they are involved in human subject research to assure that they are in compliance with existing policies, procedures, guidelines and regulations.

c. Data collected from research subjects may not be incorporated into a personnel file of the subject's employer except at the express request of the subject.

d. Only those individuals possessing appropriate security clearances and signing secrecy non-disclosure agreements may be provided with classified information appropriate to a research study. When sponsorship of research is not to be disclosed to research subjects because of security considerations such subjects shall be informed that the sponsor does not wish to be identified.

e. In cases in which the legality or propriety of any aspect of research on human subjects for intelligence purposes is not clear, Intelligence Community authorities shall seek counsel from available intelligence oversight mechanisms provided for in Section 5 of the Executive Order, i.e., Agency General Counsels, Offices of the Inspector General, and finally, the Intelligence Oversight Board. Additionally, departments and agencies are encouraged to contact the Office of Protection from Research Risks, DHEW, and the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, or their successor bodies for advisory assistance.

TAB

Approved For Release 2004/02/19 : CIA-RDP80M00165A000500260001-1

National Commission for the Protection of Human Subjects
of Biomedical and Behavioral Research

Westwood Building, Room 125
5333 Westbard Avenue
Bethesda, Maryland 20016

August 23, 1977

Mr. Walter Elder
Executive Secretary
National Foreign Intelligence Board
Intelligence Community Staff
Washington, D.C. 20505

Dear Mr. Elder:

On June 10, 1977, the Commission reviewed revised draft "Guidelines for Human Subject Research Within the Intelligence Community" and attachments thereto which you forwarded to us for comment. Some Commission members expressed concern regarding classified research conducted or supported by the Intelligence Community, and they requested clarification from your staff before commenting on the draft. On July 8, Lt. Col. Arkadie Novickoff and Dr. Salvatore Cianci testified before the Commission, explaining the nature of research conducted or supported by the Intelligence Community and the purpose of classifying some of such research as secret. Following consideration of this testimony, as well as a review of the proposed directive, the Commission offers the following comments on the draft "Guidelines."

The revised directive is a clear improvement over the first draft (dated 16 December 1976) and reflects most of the previous comments of this Commission. We appreciate the care with which your staff has responded. Our primary remaining concern is one that cannot be disposed of within the Intelligence Community itself, but would require presidential action, at a minimum, or legislation. Specifically, the Commission is concerned with the need to provide strong assurance that human rights will be protected in classified research. The mere promulgation of a directive such as the "Guidelines" may clarify the basic policies that the various intelligence agencies are expected to follow, but carries little force or authority beyond that of exhortation. Adherence to the basic policies should be required at least by Executive Order. Preferably, deviation from such policies as are established in the "Guidelines" should be prohibited by statute. Only if such steps are taken can we be reasonably assured that the well-intentioned "Guidelines" will in fact be followed by the intelligence agencies.

Our suggestions for specific modification of the "Guidelines" are as follows:

(1) When sponsorship of research is not to be disclosed for security considerations, the "Guidelines" should require that subjects be informed, as part of the information provided when their consent is solicited, that the sponsor does not wish to be identified.

(2) In the rare instances in which all aspects of a research project are classified and the research, therefore, must be reviewed by an Institutional Review Board (IRB) of which all members have security clearance, a second review of the protocol should be required. Preferably, such review would be performed by this Commission or its successor body; alternatively, it could be accomplished by the select committees in Congress having oversight of Intelligence Community operations. This would strengthen monitoring of the Intelligence Community's research activities, and, secondarily, enhance public confidence.

(3) The duties of the "resident expert," as described in Section 5(b), should be expanded to include review of the composition and operations of IRBs reviewing Intelligence Community research, when such IRBs do not have approved assurances on file with DHEW. In addition, the "resident expert" should be designated, at least for intramural research, as a person to be contacted by subjects in the event of adverse effects attributable to participation in research.

(4) The "Guidelines" should require the maintenance by appropriate authorities of records identifying subjects of drug research or other research presenting risk of harm that may not become known until after the research has been conducted. This would enable subjects to be contacted for follow-up examinations and would facilitate corroboration of claims of research-related injury.

We appreciate your openness and cooperation in developing this directive and your sensitivity to the problems of protecting human subjects. The "Guidelines" are, with the few exceptions noted above, a fine example of protective requirements; our major concern, as I have indicated, is the absence of clear authority to require compliance. We shall transmit this concern directly to the President and the appropriate Congressional committees, since we appreciate the fact that it is not within your authority to respond to them.

Thank you for the opportunity to review and comment on the draft "Guidelines"; your staff should be complimented for a fine job.

Sincerely yours,

Kenneth J. Ryan, M.D.
Chairman